Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

Protocol summary

Study aim
The effects of routine treatment and manual therapy in patients with temporomandibular disorders

Design
This study included two groups: control group and intervention group. study design: randomized control trial with control group, parallel group. The patients and outcome assessor will be blind

Settings and conduct
Place of study: Iran University of Medical Sciences, School of rehabilitation, Ultrasonography laboratory Method: This study included two groups: control group and intervention group. Control group: The control group will receive the routine physiotherapy including gentle massage over the masseter muscle, ultrasound 1 MHz and TENS. The intervention group will receive the routine physiotherapy AND manual therapy of temporomandibular joint and upper cervical .

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-unilateral or bilateral TMD according to the DC/TMD 2-pain more than 3 based on visual analog scale Exclusion criteria: 1-a traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months 2-history of the orofacial surgery during the last 6 months 3-neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

Intervention groups
Control group: The control group will receive the routine physiotherapy such as massage, therapeutic ultrasound 1MHZ and TENS for eight weeks. Intervention group: The intervention group will receive the routine physiotherapy and manual therapy of TMJ and cervical spine. The patients in both groups will receive routine physiotherapy 10 sessions during eight weeks.

Main outcome variables
pain; maximum mouth opening, cervical flexion and extension range of motions,

General information

Reason for update
Lack of time in coronary conditions

Acronym

IRCT registration information
IRCT registration number: **IRCT20190621043964N1**
Registration date: **2019-06-29, 1398/04/08**
Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**
Update count: **1**

Registration date
2019-06-29, 1398/04/08

Registrant information

Name
Khaled Rezaie

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-01, 1398/08/10

Expected recruitment end date
2021-02-01, 1399/11/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

Public title
The effects of routine treatment and manual therapy in people with temporomandibular disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with tunilateral or bilateral TMD according to the DC/TMD pain more than 3 based on visual analog scale
Exclusion criteria:
traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months history of the orofacial surgery during the last 6 months neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Block balanced randomization design, block size:4, ratio 1:1 Randomization tool: Random allocation will be performed using the website of www.randomization.com.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-10-28, 1397/08/06

Ethics committee reference number
Ir.Iums.Rec.1397.1054

Health conditions studied

1

Description of health condition studied
Temporomandibular dysfunction

ICD-10 code
M26.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
pain

Timepoint
At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Maximum mouth opening

Timepoint
At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement
caliper

2

Description
Cervical flexion and extension ROM

Timepoint
At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement
Goniometer

Intervention groups

1

Description
Control group: The control group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS for ten sessions during 8 weeks.
Category
Rehabilitation

2

Description
Intervention group: The intervention group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS and manual therapy of the TMJ and upper cervical spine. This group will receive the interventions for ten sessions during 8 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Khaled Rezaie
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The original data is shared in thesis format

When the data will become available and for how long
After defense of thesis, the original data is shared in thesis format.

To whom data/document is available
Academic researchers, physiotherapists

Under which criteria data/document could be used
In order to use clinical results, the original data is shared in thesis format.

From where data/document is obtainable
Library of the faculty of rehabilitation rehabilitation Sciences of Iran University of Medical Sciences

What processes are involved for a request to access data/document
Referral to library of the faculty of rehabilitation Sciences of Iran University of Medical Sciences

Comments